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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,878

05/25/2006

Jeremy W. Snow

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Rutan & Tucker, LLP.

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SUITE 1400

COSTA MESA, CA 92626

EXAMINER

GILBERT, ANDREW M

ART UNIT

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3767

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,878	Applicant(s) SNOW ET AL.	
	Examiner ANDREW M. GILBERT	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/22/2010 has been entered.

Acknowledgments

1. This office action is in response to the reply filed on 7/22/2010.
2. In the reply, the applicant amended claim 1 and cancelled claims 28-60.
3. Thus, claims 1-27 are pending for examination.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe how the drag force providing all of the energy for rotation of the binding member. Here, the

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applicant's specification discloses the "drag force in conjunction with one of the blocking members 116 and/or 117, cause binding member 105 to move into a binding position. The force created by blocking members 116 and/or 117 acts in a direction opposite to the drag force. This causes a force couple, which moves the binding member 105 to the binding position." This is not a teaching that the binding member has at least one drag inducing member that engages needle to create a drag force with the needle, the drag force providing all of the energy for rotation of the binding member. The applicant has explicitly disclosed that the drag force acts in conjunction with the blocking members 116 and/or 117 that create a force to move to the binding member into a binding position. Thus, the drag force does not provide all of the energy. Further, a user pulls the needle and needle hub proximally to cause the binding member to slide along the needle to cause the binding member to become in position to move into a binding position. This force by the user means the drag force does not provide all of the energy for rotation of the binding member because without the user's applied force the binding member could never find itself in a binding position.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-13 and 15-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaba (US 5,697,907).

Gaba teaches (see Fig 9 and 13-15):

A needle hub (202) having a needle cannula (132, Fig 13); and at least one shield (340),

The shield including a binding member (348) defining binding surfaces (362) that form an aperture,

The binding member including at least one drag inducing member (356, 358, and 364) providing a drag force providing energy for rotation of the binding member relative to a longitudinal axis of the needle (see response to arguments);

The binding member further including a needle communicating surface (360),

A retainer for engagement with the needle hub (see friction fit of shield with hub, Fig 8),

The binding member further including a binding member reset surface (354) alignable with a reset surface (232).

As to claim 2, see cavity 364. As to claim 3, see plate 356. As to claim 4, see arms 358 and 360. As to claim 5, 13 arm 360 is deflectable. As to claims 6, 15, 16, 17 see Fig 13-14. As to claim 7, 8 see blocking member 352. As to claim 9, see bearing 346, which causes the shield to rotate relative to the binding member. As to claim 10, see handle 202/294, Fig 9. As to claim 11, 12, 22 see Fig 8-9. As to claim 18, the spring 352

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pinches the reset surface (232) and binding member reset surface (354) together (Fig 13), thereby urging the reset surface towards the binding member reset surfaces. As to claim 19, see taper 222. As to claim 20, see sheath 350. As to claim 21, 23 see guide 344. As to claims 24, 26, see funnel 144 on shield 300. As to claim 25, see detent 326, Fig 10. As to claim 27, see stop 344.

2. Claims 1-23, 25, 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Carlyon et al (7226434). Carlyon discloses a needle hub 52 having a needle cannula (22); and at least one shield (48),

The shield including a binding member (28) defining binding surfaces (35, 62 Fig 3-7) that form an aperture,

The binding member including at least one drag inducing member (42, 30) providing a drag force providing energy for rotation of the binding member relative to a longitudinal axis of the needle (Fig 3-7);

The binding member further including a needle communicating surface (34),

A retainer for engagement with the needle hub (see friction fit of shield with hub, 52 and 44 Fig 6),

The binding member further including a binding member reset surface (70) alignable with a reset surface (72).

3. As to claim 2, see cavity 34. As to claim 3, see plate 60. As to claim 4, see arms 74, 64. As to claim 5, arms 74, 64 are deflectable. As to claims 6, 15, 16, 17 see Fig 3-7. As to claim 7, 8 see shield 48 and blocking members 78. As to claim 9, see bearing

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78, which causes the shield to rotate relative to the binding member. As to claim 10, see handle 52. As to claim 11, 12, 22 see Fig 6-7. As to claim 18, the binding member spring arms urge the reset surface (72) and binding member reset surface (70) together (Fig 6), thereby urging the reset surface towards the binding member reset surfaces. As to claim 19, see taper 52. As to claim 20, see front face of 48 having aperture. As to claim 21, 23 see front face of 48 having aperture. As to claim 25, see Fig 6. As to claim 27, see 84, 68 and front face of 48.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gaba as applied to claims above, and further in view of Dombrowski et al (US 4,978,344).

Gaba does not teach multiple shields. Dombrowski teaches a shield (34) with sheath (50"). See Fig 7. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include multiple shield to protect the user from both the tip of the needle and from residual fluids on the sides of the needle.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 7179244.

Although the conflicting claims are not identical, they are not patentably distinct from

each other because the claims in the present application are merely broader than the copending parent case. Thus, the invention claimed in the current application is merely generic to the species claimed in the parent application and it has been held that the generic invention is anticipated by the species.

Response to Arguments

1. Applicant's arguments filed 7/22/2010 have been fully considered but they are not persuasive. Applicant argues against the 35 USC 112(¶1) rejection, but is not persuasive for reasons stated above.
2. Applicant argues that Gaba does not teach the binding member including at least one drag inducing member (356, 358, and 364) providing a drag force providing all of the energy for rotation of the binding member relative to a longitudinal axis of the needle. First, the applicant does not have written description support for all of the energy, so the examiner has interpreted the claims as providing energy for rotation. Second, the engagement of the needle and 348 creates the drag force. This drag force is increased via spring 352 which prevents or blocks the binding member from rotating clockwise. Thus it can reasonably be said that binding member 348 provides a drag force that provides energy for rotation of the binding member.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/
Examiner, Art Unit 3767

/Theodore J Stigell/
Primary Examiner, Art Unit 3763